UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,603	02/05/1999	DAVID T. CURIEL	D6080	5072

27851 7590 10/07/2003

BENJAMIN A. ADLER
8011 CANDLE LANE
HOUSTON, TX 77071

EXAMINER	
PARAS JR, PETER	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/07/2003 23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/245,603	CURIEL ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9,11,16,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,11,16,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's amendment received on 7/21/03 has been entered. Claims 1, 11, and 16 have been amended. Claim 12 has been cancelled. Claims 1-4, 9, 11, 16 and 22-23 are pending and are under current consideration.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 9, 11-12 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as amended now recites that the fiber knob and said fiber gene are from the same serotype and is unclear as written. The specification has disclosed that the fiber gene encodes the fiber knob so it is unclear how the fiber gene and fiber knob could be anything other than the same serotype. So if the fiber gene is modified then the fiber knob is likewise modified. Furthermore, the serotype of an adenovirus is based on its wild-type fiber knob. Any modification of the fiber knob changes the serotype from wild-type. So it is unclear what the serotype of such a modified fiber knob may be. Claims 2-4, 9 and 11 depend from claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined

under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 9, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Wickham et al. The previous rejection is maintained for the reasons of record advanced on pages 3-5 of the Office action mailed on 2/26/03.

Applicants arguments filed on 7/21/03 have been fully considered but are not found persuasive. Applicants contend that Wickham does not anticipate the claimed invention, in particular because Wickham allegedly taught exchanging the fiber knob of Ad5 with the knob coding region from Ad2. Applicants assert the instantly claimed invention differs from Wickham as it is directed to a modified adenovirus comprising a fiber knob and fiber shaft from the same serotype. See pages 11-13 of the amendment.

In response, the Examiner asserts that the claimed invention is directed to a modified adenovirus comprising a fiber gene and fiber knob of the same serotype. The Examiner submits Applicant's arguments are off-point as the claims as written do not require (or cannot be interpreted to require) that the fiber knob and fiber shaft be of the same serotype. Furthermore, the serotypes are based on wild-type fibers. Since the claimed adenovirus comprises a modified fiber gene and fiber knob no readily apparent serotype of the adenovirus is discernible. Moreover, adenoviruses comprising a fiber knob of Ad2 and a fiber shaft of Ad5 are not the only adenoviruses taught by Wickham; it appears that Wickham has also taught adenoviruses comprising non-native insertions in the

HI loop, wherein the adenoviruses comprise a fiber shaft and fiber knob of the same serotype. See examples 2-4.

Applicants also have argued that Wickham et al has taught a different adenoviral modification in which a peptide motif is attached to the C-terminal of the fiber to create a nonpreexisting loop. Applicants assert that the instantly claimed invention does not require attaching a peptide motif to the C-terminal of the fiber protein to create a nonpreexisting loop. Applicants further assert that the instantly claimed invention simply teaches inserting a peptide into the HI loop of the fiber knob. See pages 13-14 of the amendment.

In response, the Examiner maintains that Wickham et al has taught modification in the HI loop (see column 8) and that the modification can be the insertion of a nucleic acid sequence encoding an RGD peptide (see columns 9 and 27). Furthermore, the Examiner maintains that Wickham et al has taught an adenoviral vector comprising a nucleic acid sequence encoding HSV-TK (see column 14) and has also taught gene transfer in tumor cells (see column 17). The Examiner asserts that Wickham et al has taught gene transfer into tumors *in vivo* (see column 17, at lines 1-10 and lines 36-45). Moreover, in response to Applicant's argument that the disclosure of Wickham is not enabling for an adenovirus with an RGD peptide inserted into the HI loop of the fiber protein, it is understood that every patent is presumed valid (35 U.S.C. 282), and that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935). Also see MPEP 716.07. Further, since in a patent it is presumed that a process if used by one skilled in

the art will produce the product or result described therein, such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. In re Weber, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969). It is to be presumed also that skilled workers would as a matter of course, if they do not immediately obtain desired results, make certain experiments and adaptations, within the skill of the competent worker. The failures of experimenters who have no interest in succeeding should not be accorded great weight. In re Michalek, 162 F.2d 229, 74 USPQ 107 (CCPA 1947); In re Reid, 179 F.2d 998, 84 USPQ 478 (CCPA 1950). See pages 4-5 of the Office action mailed on 2/26/03.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 22-23 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al. The previous rejection is maintained for the reasons of record advanced on pages 6-7 of the Office action mailed on 2/26/03.

Applicants have argued that Wickham et al has not taught the claimed modified adenovirus as previously discussed above. See pages 15-16 of the amendment.

In response, the Examiner maintains that Wickham has taught the invention as claimed. See above. It is further maintained that Wickham has taught an adenovirus comprising a modified fiber knob is able to direct entry into cells more efficiently. See column 6. It is further maintained that Wickham has provided motivation for in vitro transduction of primary tumor cells as stated in the previous Office action on page 7. See column 15, lines 3-9 and also the paragraph bridging columns 18-19.

Accordingly, the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER